

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

PLANNED PARENTHOOD SOUTH ATLANTIC, <i>et al.</i> ,	)	
	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
JOSHUA STEIN, <i>et al.</i> ,	)	Case No. 1:23-cv-00480-CCE-LPA
	)	
Defendants,	)	
	)	
and	)	
	)	
PHILIP E. BERGER, <i>et al.</i> ,	)	
	)	
Intervenor-Defendants.	)	

**[PROPOSED] ORDER GRANTING PLAINTIFFS’ AMENDED MOTION FOR  
PRELIMINARY INJUNCTION**

Plaintiffs Planned Parenthood South Atlantic (“PPSAT”) and Dr. Beverly Gray, M.D. (together, “Plaintiffs”) have moved pursuant to Federal Rule of Civil Procedure 65 and Local Rule 65.1 for a preliminary injunction enjoining enforcement of two components of North Carolina Session Law 2023-14 (“S.B. 20,” *see* DE 1-1) (codified as amended by Session Law 2023-65 (“H.B. 190,” *see* DE 26-1) at N.C. Gen. Stat. art. 1I, ch. 90 (entitled “Abortion Laws,” here referred to as the “Act”)). Specifically, Plaintiffs seek preliminary injunctive relief against (i) N.C. Gen. Stat. §§ 90-21.81B(3), -(4), 90-21.82A(c), 131E-153.1 (the “Hospitalization Requirement”); and (ii) *id.* § 90-21.83B(a)(7) (the “IUP Documentation Requirement”).

The Court entered a temporary restraining order enjoining enforcement of the IUP Documentation Requirement, DE 31 (TRO) at 6–9, and, by consent of the parties, extended that restraining order up to the date of this ruling. DE 35 (Consent Order Extending TRO); DE 37 (Scheduling Order). The effective date of the Hospitalization Requirement is October 1, 2023. *See* DE 30 (Joint Stipulation) at 2; DE 31 (TRO) at 9. A hearing on Plaintiffs’ Amended Motion for a Preliminary Injunction (DE 48) was held on September 25, 2023.

After review of the briefing and supporting evidence submitted by all parties, as well as oral argument, this Court will grant Plaintiffs’ Amended Motion for a Preliminary Injunction as to both of the challenged requirements.<sup>1</sup>

## **BACKGROUND**

Until July 1, 2023, abortion was broadly lawful in North Carolina before 20 weeks of pregnancy and was routinely provided at licensed outpatient abortion clinics such as PPSAT’s up to the legal gestational limit. Now, under the Act, it is “unlawful after the twelfth week of a woman’s pregnancy to procure or cause a miscarriage or abortion in the

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<sup>1</sup> “When a party moves for a preliminary injunction, . . . it invites the district court to act as the finder of fact on a limited record.” *Speech First, Inc. v. Sands*, 69 F.4th 184, 190 (4th Cir. 2023). The Court notes that, “[b]ecause preliminary injunction proceedings are informal ones designed to prevent irreparable harm before a later trial governed by the full rigor of usual evidentiary standards, district courts may look to, and indeed in appropriate circumstances rely on, hearsay or other inadmissible evidence when deciding whether a preliminary injunction is warranted.” *G.G. ex rel. Grimm v. Gloucester Cnty. Sch. Bd.*, 822 F.3d 709, 725–26 (4th Cir. 2016), *vacated and remanded on other grounds*, *Gloucester Cnty. Sch. Bd. v. G. G. ex rel. Grimm*, 137 S. Ct. 1239 (2017). The declarations and deposition testimony in this case include facts and expert opinions. At this stage in the case, the Court need not rule on which facts and opinions are admissible.

State of North Carolina.” N.C. Gen. Stat. § 90-21.81A (the “Twelve-Week Ban”). While the Act creates exceptions to the Twelve-Week Ban in cases of rape, incest, or life-limiting anomalies, the Hospitalization Requirement—if it takes effect on October 1, 2023—will mandate that abortions provided after the twelfth week of pregnancy occur in a hospital. *Id.* §§ 90-21.81B(3), 90-21.81B(4), 90-21.82A(c). As to early medication abortion, the IUP Documentation Requirement states that physicians must “[d]ocument in the woman’s medical chart the . . . existence of an intrauterine pregnancy.” *Id.* § 90-21.83B(a)(7).

Providing an abortion that does not fit within the Act’s exceptions to the Twelve-Week Ban is a felony offense. *Id.* §§ 90-21.81A, 90-21.81B; *see also id.* §§ 14-44, -45, -23.7(1). Additionally, a physician who violates the Act is subject to discipline by the North Carolina Medical Board, and any other licensed health care provider who violates the Act is subject to discipline by their respective licensing agency or board. *Id.* § 90-21.88A.

## **I. The Hospitalization Requirement**

Three methods of abortion are provided in outpatient clinics in North Carolina: medication abortion, aspiration abortion, and dilation and evacuation (“D&E”). First Decl. of Katherine Farris, M.D., in Supp. of Pls.’ Am. Mot. for a Prelim. Inj. (“First Farris Decl.”) DE 49-1 ¶ 14. Medication abortion typically involves two prescription drugs: mifepristone, which blocks progesterone, a hormone necessary to maintain a pregnancy, and misoprostol, which causes the cervix to open and the uterus to contract and empty its contents. *Id.* ¶ 17. Aspiration abortion (also known as dilation & curettage (“D&C”)) entails using suction to empty the uterus. *Id.* ¶ 21. D&E uses a combination of suction and additional instruments

to empty the uterus. *Id.* ¶ 25. All of these abortion methods require no incisions and typically take no more than fifteen minutes to perform. *Id.* ¶ 14. In the outpatient setting generally and at PPSAT specifically, local, mild, or moderate sedation might be used for these procedures, but deep sedation and general anesthesia are not. First Farris Decl., DE 49-1 ¶¶ 22, 26, 72; Dep. of Katherine A. Farris (“Farris Dep.”), Pls.’ Supp. Br. Ex. 2, 88:9–25. The types of sedation offered by PPSAT are safely provided in the outpatient setting. Dep. of Dr. Susan Bane (“Bane Dep.”), Pls.’ Supp. Br. Ex. 4, 106:18–107:3, 107:15–18.

The evidence conclusively demonstrates that abortion is safe, including in outpatient clinics—safer than other medical procedures that are routinely performed outside of hospital settings in North Carolina, including vasectomies, colonoscopies, wisdom tooth extractions, and tonsillectomies. First Farris Decl., DE 49-1 ¶ 32. A study relied upon by both of Intervenor-Defendants’ experts describes abortion as “generally safe.” Decl. of Monique Chireau Wubbenhorst, M.D., M.P.H. (“Wubbenhorst Decl.”), DE 65-1 ¶¶ 32–35; Decl. of Susan Bane, M.D., Ph.D (“Bane Decl.”), DE 65-3 ¶ 35; Bane Dep. 72:15–20. Another study demonstrated that second-trimester terminations of pregnancy by D&E in appropriate patients in a dedicated outpatient facility can be safer and less expensive than hospital-based D&E or induction of labor. First Farris Decl., DE 49-1 ¶ 38 & n.30; *see also* Dep. of Dr. Monique Wubbenhorst (“Wubbenhorst Dep.”), Pls.’ Supp. Br. Ex. 3, 131:22–132:1 (study cited by Dr. Wubbenhorst concluded that D&Es performed in non-hospital settings had lower death rates than those performed in hospitals). PPSAT has safely provided abortions in its licensed outpatient clinics past the twelfth week of pregnancy for

more than fifteen years in North Carolina. First Farris Decl., DE 49-1 ¶ 12; Farris Dep. 75:4–6.

Abortion is approximately twelve to fourteen times safer than live birth. First Farris Decl., DE 49-1 ¶ 34. Hospitalization is not required for childbirth under North Carolina law, as the Act itself recognizes. N.C. Gen. Stat. § 90-178.4 (as amended by S.B. 20, § 4.3(d), effective Oct. 1, 2023) (providing for “planned birth outside of a hospital setting”). North Carolina law also does not require hospitalization for miscarriage management after the twelfth week of pregnancy, and many of the procedures used for miscarriage management are clinically identical to the procedures used for abortion. *See* First Farris Decl., DE 49-1 ¶ 41; Bane Dep. 28:12–17 (medication used for miscarriage management), Bane Dep. 29:18–20 (D&Cs used for miscarriage management); Wubbenhorst Dep. 114:19–21 (same).

Complications from abortion are extremely rare, and the vast majority are easily treatable in outpatient facilities. PPSAT performed 38,795 abortions in North Carolina between January 1, 2020 and June 30, 2023; only 522 complications resulted, most of which were minor. Rebuttal Decl. of Katherine Farris, M.D. in Supp. of Pls.’ Am. Mot. for a Prelim. Inj. (“Farris Rebuttal Decl.”) DE 69-2 ¶ 8; Bates 0106, Pls.’ Supp. Br. Ex. 13. Major abortion complications, defined as those requiring hospital admission, surgery, or blood transfusion, occur in just 0.23% of abortions. First Farris Decl., DE 49-1 ¶ 31. PPSAT’s transfer rate is lower than that rate; it transferred 0.08% of its 38,795 North Carolina abortion patients to hospitals in three and a half years. Farris Rebuttal Decl., DE

69-2 ¶ 8; Bates 0051–0052, Pls.’ Supp. Br. Ex. 12; Bates 0106; Bates 0107, Pls.’ Supp. Br. Ex. 14. All were released in stable condition, and only 7 out of the 31 patients transferred were admitted. Farris Rebuttal Decl., DE 69-2 ¶ 8; Bates 0051–0052; Bates 0106; Bates 0107. PPSAT has relationships with hospitals near its clinics and emergency management protocols for the rare event that hospital transfer is needed. Farris Rebuttal Decl., DE 69-2 ¶ 8.

Specifically, hemorrhage, infection of the uterine lining, cervical lacerations, and uterine perforation are rare and can all be treated in outpatient facilities. *See* Farris Rebuttal Decl., DE 69-2 ¶¶ 5–7; Farris Dep. 65:2–8; Dep. of Christy Marie Boraas Alsleben, MD (“Boraas Dep.”), Pls.’ Supp. Br. Ex. 1, 170:17–171:15, 171:21–173:7; *accord* Bane Dep. 94:18–95:1 (discussing outpatient treatment of endometritis), 104:20–23 (discussing outpatient treatment of cervical lacerations). The same complications can also arise during miscarriage management and childbirth, and indeed are more likely to occur during childbirth than during abortion. *E.g.* First Farris Decl., DE 49-1 ¶ 33; Boraas Dep. 92:3–10 (pulmonary embolism “is extremely rare after a person has an induced abortion. It is much more common and likely after giving birth”); 173:8–175:5 (“Hemorrhage requiring a blood transfusion is much more likely at the time of giving birth either vaginally or by a cesarean section than it would be for a person accessing induced abortion.”); *accord* Bane Dep. 26:5–9 (explaining that risks of miscarriage management include hemorrhage; infection; uterine perforation; and even death); *see also id.* at 94:4–13; 100:5–16; 101:16–23; 103:17–21 (testifying that “usually childbirth” is where cervical lacerations occur).

## II. The IUP Documentation Requirement

There are five categories that physicians use when evaluating an early pregnancy via ultrasound: definite intrauterine pregnancy, probable intrauterine pregnancy, probable ectopic pregnancy (i.e., a pregnancy that has implanted outside of the uterus), definite ectopic pregnancy, and pregnancy of unknown location. Farris Dep. 102:22–103:6; Boraas Dep. 127:6–16. In the earliest weeks of pregnancy—up to approximately the fifth or sixth week of pregnancy, as dated from the first day of the patient’s last menstrual period—pregnancy tissue may not yet be seen even by transvaginal ultrasound. Patients in this situation, who have positive pregnancy tests but no pregnancy tissue visible on an ultrasound, are categorized as having pregnancies of unknown location. First Farris Decl., DE 49-1 ¶ 9. If the IUP Documentation Requirement requires PPSAT to document that an intrauterine pregnancy is visible by ultrasound before providing a medication abortion, it would prohibit PPSAT from providing medication abortion to these patients who are very early in their pregnancies.<sup>2</sup>

Intervenors defend their interpretation of the IUP Documentation Requirement by stating that mifepristone is “contraindicated” for ectopic pregnancies. While mifepristone is contraindicated for suspected or confirmed ectopic pregnancy, the contraindication

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<sup>2</sup> While it is unclear on the face of the statute whether the IUP Documentation Requirement actually requires visual confirmation of an IUP by ultrasound, *see infra* Analysis Section I.B.i, intervenors take the position that visual confirmation by ultrasound is required to comply with the requirement. *See* Def.-Intervenors’ Resp. in Opp. to Pls.’ Am. Mot. for Prelim. Inj. (“Int. Resp.”) DE 65 at 20.

exists not because mifepristone harms patients with ectopic pregnancies but because mifepristone does not treat ectopic pregnancy. Rebuttal Decl. of Christy M. Boraas Alsleben, M.D., M.P.H. in Supp. of Pls.’ Am. Mot. for a Prelim. Inj. (“Boraas Rebuttal Decl.”) DE 69-1 ¶ 50; Farris Dep. 155:11–14; Wubbenhorst Dep. 143:19–21. Mifepristone is not contraindicated for patients where ectopic pregnancy is not suspected. *See* FDA Mifeprex Label, DE 65-2 at 4; *see also* Farris Dep. 102:22–103:6, 108:2–7, 110:10–19, 162:3–14, 168:17–23; Boraas Dep. 127:6–16, 145:20–146:1.

North Carolina requires an ultrasound prior to every abortion. 10A N.C. Admin. Code 14E.0305(d), *replaced by* 10A N.C. Admin. Code 14E.0321(d) (effective July 1, 2023). If a pregnancy is not visible on the ultrasound, PPSAT screens the patient for risk of ectopic pregnancy by asking questions about their menstrual history, pregnancy history (including history of prior ectopic pregnancy), contraceptive history, and any symptoms they are experiencing. First Farris Decl., DE 49-1 ¶ 52; Farris Rebuttal Decl., DE 69-2 ¶ 12; Farris Dep. 137:9–15, 86:6–8; 111:4–11, 162:15–163:13. If PPSAT determines that the patient is at high risk of ectopic pregnancy, the patient is not eligible for an abortion at that time and is immediately referred to another provider, typically an emergency department, for diagnosis and treatment. First Farris Decl., DE 49-1 ¶ 52; Farris Dep. 107:3–8, 109:14–21, 110:5–9, 163:8–17.

If the patient is *not* at high risk of ectopic pregnancy, the provider offers the patient three options: medication abortion, aspiration abortion, or a follow-up appointment to see if an intrauterine pregnancy can be seen on an ultrasound at a later date. First Farris Decl.,

DE 49-1 ¶ 53; Farris Dep. 163:18–164:8. If a low-risk patient chooses medication abortion, PPSAT simultaneously provides the medication abortion and conducts further testing to rule out ectopic pregnancy, the first step of which is drawing a blood sample to test the level of the pregnancy hormone human chorionic gonadotropin (“hCG”). First Farris Decl., DE 49-1 ¶ 54; Farris Dep. 164:9–24.

If a patient’s initial blood test results indicate that their hCG levels are sufficiently high, PPSAT considers this evidence of potential ectopic pregnancy and provides further evaluation and treatment accordingly, including potential referral to an emergency department, even though the patient has already taken the abortion medications. First Farris Decl., DE 49-1 ¶ 55. If the hCG levels are not high, the patient’s hCG levels are tested again 48-72 hours after taking the misoprostol. *Id.* ¶ 56. If the pregnancy hormone levels have dropped following the medication abortion, this is evidence that the abortion is complete. *Id.* ¶ 57. But if the patient’s hormone levels remain high or have increased even after the patient has taken the abortion medications, this is evidence that no abortion has occurred and PPSAT conducts further evaluation for ectopic pregnancy, including referral as medically indicated. *Id.* ¶ 57.

All patients treated using this protocol are educated on signs and symptoms of both medication abortion and ectopic rupture—which both parties’ experts agree are typically distinguishable<sup>3</sup>—and they are warned both verbally and in writing that untreated ectopic

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<sup>3</sup> Generally speaking, patients experiencing ectopic rupture feel sharp pain that is often located on one side of the lower abdomen, as opposed to the more general cramping that miscarriage and medication abortion patients experience; additionally, patients typically

pregnancy could result in death. Farris Rebuttal Decl., DE 69-2 ¶ 12; Bates 0119–0120, Pls.’ Supp. Br. Ex. 15.

PPSAT’s protocol is evidence-based and has been shown to be safe and effective. *See* Decl. of Christy M. Boraas Alsleben, M.D., M.P.H. in Supp. of Pls.’ Am. Mot. for a Prelim. Inj. (“First Boraas Decl.”) DE 49-2 ¶¶ 44–47. One study found that this protocol leads to earlier exclusion of ectopic pregnancy than waiting to see whether an intrauterine pregnancy can be diagnosed. *Id.* ¶ 46 & n.23; Boraas Rebuttal Decl., DE 69-1 ¶ 49 & n.61. Intervenor-Defendants’ experts agree that ectopic screening protocols that use ultrasounds, medical histories, and serial hCG testing are appropriate. Bane Dep. 117:22–118:25, 143:4–11; Wubbenhorst Dep. 143:22–25. Dr. Bane testified that if a patient presented with a positive pregnancy test but had no symptoms, she would wait until six to seven weeks of pregnancy to do an ultrasound and would not refer a stable patient to the ER, even if they had minor complaints such as “abdominal pain or some bleeding.” Bane Dep. 117:22–118:25.

## ANALYSIS

A preliminary injunction is warranted upon a showing that: “(1) the party is likely to succeed on the merits of the claim; (2) the party is likely to suffer irreparable harm in the absence of an injunction; (3) the balance of hardships weighs in the party’s favor; and

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have less vaginal bleeding during ectopic rupture than they do during miscarriage or medication abortion. Boraas Rebuttal Decl., DE 69-1 ¶ 53; Wubbenhorst Dep. 182:16–25; Bane Dep. 120:3–5, 120:17.

(4) the injunction serves the public interest.” *HIAS, Inc. v. Trump*, 985 F.3d 309, 318 (4th Cir. 2021). Plaintiffs have met their burden on each of these four factors.

## **I. Likelihood of Success on the Merits**

### **A. The Hospitalization Requirement**

Plaintiffs argue that the Hospitalization Requirement violates the Fourteenth Amendment’s Due Process and Equal Protection Clauses. They argue that for abortions permitted after the twelfth week of pregnancy under the Act—namely abortions in cases of rape, incest, or life-limiting anomaly—there is no rational basis for restricting access to abortion by requiring that these abortions be performed in a hospital. The Court agrees.

Under *Dobbs v. Jackson Women’s Health Org.*, 142 S. Ct. 2228 (2022), there is no longer a fundamental right to abortion under the substantive due process component of the Fourteenth Amendment. Therefore, this Court applies rational basis review to Plaintiffs’ due process challenge, as it would to a restriction on any other medical procedure. *See Doe v. Settle*, 24 F.4th 932, 943–44, 953 (4th Cir. 2022) (“A substantive due process challenge is considered under rational-basis review unless some fundamental right is implicated.”).

With respect to equal protection, Plaintiffs argue that the Act singles out for unequal treatment physicians who provide, and patients who seek, abortion in outpatient settings after the twelfth week of pregnancy because of rape, incest, or life-limiting anomaly, compared to those who provide or seek medical procedures of equal or greater risk, including miscarriage management at the same gestational age. Because Plaintiffs do not allege that the Act discriminates against a protected class, the Court applies rational basis

review to this claim as well. *See Wilkins v. Gaddy*, 734 F.3d 344, 347 (4th Cir. 2013) (“[U]nless a statute affects a fundamental right or some protected class, courts generally accord the legislation a ‘strong presumption of validity’ by applying a rational basis standard of review.” (quoting *Heller v. Doe*, 509 U.S. 312, 319 (1993))).

The rational basis standard is “quite deferential,” and a statute passes constitutional muster if it is, “at a minimum, rationally related to legitimate governmental goals.” *Wilkins*, 734 F.3d at 347, 348; *see also Dobbs*, 142 S. Ct. at 2284 (holding abortion restrictions “must be sustained if there is a rational basis on which the legislature could have thought it would serve legitimate state interests.”). In engaging in the rational basis inquiry, the Court need not determine whether the interest proffered by the government is the “actual reason” for the legislation. *McDaniels v. U.S.*, 300 F.3d 407, 412 n.2 (4th Cir. 2002); *see also U.S. R.R. Ret. Bd. v. Fritz*, 449 U.S. 166, 179 (1980).

However, the rational basis standard is “not a toothless one.” *Mathews v. Lucas*, 427 U.S. 495, 510 (1976). A “bare [legislative] desire to harm a politically unpopular group cannot constitute a legitimate governmental interest.” *U.S. Dep’t of Agric. v. Moreno*, 413 U.S. 528, 534 (1973). And courts engaged in rational basis review may and should “consider plaintiffs’ extrinsic evidence” and conduct fact-finding to determine the realities underlying the challenged regulation and the proffered justification. *Trump v. Haw.*, 138 S. Ct. 2392, 2420 (2018); *see also U.S. v. Carolene Prods. Co.*, 304 U.S. 144, 153 (1938) (“Where the existence of a rational basis for legislation whose constitutionality is attacked depends upon facts beyond the sphere of judicial notice, such facts may properly be made

the subject of judicial inquiry.”); *see also Planned Parenthood of Ind. & Ky., Inc. v. Comm’r, Ind. Dep’t of Health*, 64 F. Supp. 3d 1235, 1257 (S.D. Ind. 2014) (“[Supreme Court precedent] does not . . . authorize the unequal treatment of those providing the exact same procedure, without a rational basis, and equal protection demands otherwise.”).

The Court therefore turns to the question of whether, based on the facts presented by the parties, the Hospitalization Requirement is rationally related to the governmental interest in patient safety. Intervenor-Defendants argue that hospitals are better equipped to address complications that may arise from procedural abortions, which include hemorrhage, infection, cervical laceration, uterine perforation, sepsis, and death, and that the Hospitalization Requirement therefore furthers patient safety. While furthering patient safety is certainly a legitimate governmental interest, the operative inquiry here is not whether there are differences between outpatient clinics and hospitals, but whether the differences matter for purposes of providing abortion safely after the twelfth week of pregnancy. Reply in Supp. of Pls.’ Am. Mot. for Prelim. Inj. (“Pl. Reply”), DE 69 at 4; *see Catherine H. Barber Mem’l Shelter, Inc. v. Town of N. Wilkesboro Bd. of Adjustment of Town of N. Wilkesboro*, 576 F. Supp. 3d 318, 338, 341 (W.D.N.C. 2021). The Court concludes that they do not.

Plaintiffs have presented evidence that procedural abortion is as safe as or safer than a broad range of other medical procedures routinely performed in outpatient settings, including other gynecological procedures like endometrial biopsy and hysteroscopy. First Farris Decl., DE 49-1 ¶¶ 32, 40. And abortion procedures after twelve weeks—both

aspiration and D&E—are nearly identical to procedures for managing miscarriage at the same gestational age, which can be provided in outpatient settings. *Id.* ¶¶ 24, 28, 40. In fact, Intervenor-Defendants’ expert Dr. Bane conceded that the complications from miscarriage procedures are extremely similar to those for abortion procedures. Bane Dep. 26:5–9.

Plaintiffs have also introduced evidence that complications from procedural abortion are rare and can nearly always be managed at outpatient clinics, with no need for hospitalization. First Farris Decl., DE 49-1 ¶ 41. Serious complications requiring hospitalization occur in 0.23% of all abortions performed in outpatient settings, and the PPSAT-specific rate is even lower; when such complications occur, PPSAT has established procedures to ensure patients are safely transferred to a hospital. *Id.* ¶¶ 31, 43; Farris Rebuttal Decl., DE 69-2 ¶ 8. The risk of death is lower still; the mortality rate for legal abortions—the vast majority of which are not provided in hospitals—is 0.43 per 100,000 procedures, making abortion at least twelve times safer than childbirth. First Farris Decl., DE 49-1 ¶ 34.

The Court finds persuasive Plaintiffs’ evidence that procedural abortion after twelve weeks is as safe as or safer than medical procedures routinely performed in outpatient environments, that it is nearly identical in risk and technique to miscarriage care, that complications requiring hospitalization are extremely rare, and that PPSAT safely transfers patients to hospitals in such cases. While Intervenor-Defendants have offered competing evidence, *see, e.g.*, Bane Decl., DE 65-3 ¶¶ 31-41, the sources they rely on do not show

causal links between abortion and increased mortality, and some actually affirm the finding that abortion is safe. *See* Bane Dep. 67:4–9 (causation cannot be established with abortion studies), 72:15–20 (conceding that study cited by Intervenor-Defendants’ experts found that abortion is “generally safe”), 61:25–62:4 (conceding that cited study found extremely low death rates for legally induced abortions). The Court is also concerned by the bias expressed by Intervenor-Defendants’ experts.<sup>4</sup> *See Underwood v. Elkay Min, Inc.*, 105 F.3d 946, 951 (4th Cir. 1997), *superseded on other grounds by Mountaineer Coal Dev. Co., Inc. v. Dingess*, 538 F. App’x 367 (4th Cir. 2013) (in considering expert opinions, courts should examine “the qualifications of the experts, the opinions’ reasoning, their reliance on objectively determinable symptoms and established science, their detail of analysis, and their freedom from irrelevant distractions and prejudices”). The Court therefore credits Plaintiffs’ experts’ testimony, which is supported by the National Academies of Sciences, Engineering, and Medicine, as well as major medical associations including the American College of Obstetricians and Gynecologists (“ACOG”) and the American Public Health

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<sup>4</sup> Dr. Wubbenhorst opposes abortion in all circumstances, including in cases of rape or incest (the circumstances under which the Hospitalization Requirement applies); she believes that doctors who provide abortion are committing murder; and she believes that “all” abortions, even those with no medical complications, cause harm to women. Wubbenhorst Dep. 31:2–5, 31:23–32:4, 31:20–22, 33:24–35:9. Dr. Bane referred to herself as a “pro-life advocate,” repeatedly described abortion as the “direct and intentional killing of a human being,” and dramatically minimized the health risks of childbirth by saying that people “rarely” struggle with anxiety and depression after giving birth. Bane Dep. 84:18–19, 13:1–2, 40:15–16, 79:22–80:1.

Association, which have all made clear that hospitalization requirements for abortion lack any scientific or medical basis. First Farris Decl., DE 49-1 ¶ 37.<sup>5</sup>

Plaintiffs have also introduced evidence that D&E procedures in a dedicated outpatient abortion facility can in fact be *safer* than the same procedures provided in a hospital and that fewer complications from abortion are seen in outpatient clinics that routinely provide abortions than in hospitals, many of which do not routinely provide abortion. *Id.* ¶¶ 38, 74. Intervenor-Defendants state that Dr. Farris cites a news article and not a scientific research paper for these points, but Dr. Farris does in fact cite a research paper for the conclusion that “D&E in appropriate patients in a dedicated outpatient facility can be safer and less expensive than hospital-based D&E or induction of labor.” *Id.* ¶ 38 & n.30 (citing David K. Turok et al., *Second Trimester Termination of Pregnancy: A Review by Site and Procedure Type*, 77 *Contraception* 155, 155 (2008)). More to the point, Intervenor-Defendants do not offer any evidence to the contrary. In fact, Dr. Wubbenhorst admitted that a study she cited concluded that D&Es performed in nonhospital settings had *lower* death-to-case rates than those performed in hospitals. Wubbenhorst Dep. 131:22–132:1. The Court credits Dr. Farris’s testimony on this point.

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<sup>5</sup> Intervenor-Defendants correctly argue that the State is not required to defer to the policy choices of professional organizations. But the Court finds that the opinions of medical associations are relevant to the question of whether hospitalization requirements actually further patient safety. The Court further notes that Intervenor-Defendants’ experts relied on ACOG publications in their declarations. *See, e.g.*, Wubbenhorst Decl., DE 65-1 ¶ 105, Bane Decl., DE 65-3 ¶¶ 56–68.

Further, the Hospitalization Requirement applies *only* to survivors of rape or incest and patients with life-limiting fetal diagnoses. It therefore makes accessing abortion harder for people whose pregnancies are causing them immense hardship. As Plaintiffs' experts testified, survivors of sexual violence are often dealing with trauma, and specialized outpatient clinics can be better equipped to serve such patients. First Farris Decl., DE 49-1 ¶¶ 65–67, 75; First Boraas Decl., DE 49-2 ¶ 36. They also may be better equipped to serve patients with fetal anomalies, which are often diagnosed after twelve weeks of pregnancy; indeed, hospital providers in North Carolina sometimes refer patients with fetal anomalies to PPSAT. First Farris Decl., DE 49-1 ¶¶ 8, 46, 68.

Finally, Plaintiffs have introduced evidence that requiring hospitalization creates additional burdens for patients and usually delays patient care. First Farris Decl., DE 49-1 ¶¶ 70–72; Farris Dep. 162:4–14. Both sides' experts agree that the risks associated with abortion increase as gestation progresses. Boraas Rebuttal Decl., DE 69-1 ¶ 19; Wubbenhorst Decl., DE 65-1 ¶ 38; Bane Decl., DE 65-3 ¶ 35. Faced with the difficult circumstances of rape, incest, or fetal anomaly, a patient's pain and suffering may be prolonged and increased by a delay accessing an abortion they have already chosen. Increased delay is detrimental to patients' health and safety. Farris Dep. 164:25–165:10 (requiring hospitalization undermines safety because it usually delays patient care and the risk of abortion increases with gestational age, though abortion is very safe overall).

In summary, based on the evidence in this case, the Court finds that procedural abortions after the twelfth week of pregnancy are as safe as or safer than other procedures

provided in outpatient settings, including miscarriage management, which involve nearly identical risks; that leading medical associations have concluded that there is *no* safety rationale for hospitalization requirements, including in the second trimester; and that procedural abortions at outpatient clinics may in fact be safer and more patient-friendly than those at hospitals. Thus, the Court concludes that Plaintiffs have shown they are likely to succeed on their claim that the Hospitalization Requirement is not rationally related to the State's legitimate interest in patient safety. The mere fact that, like any other medical procedure, a small number of complications requiring hospitalization will occur is not sufficient to establish this rational relationship, absent a showing that performing the procedure itself in a hospital actually promotes safety. *See, e.g., O'Day v. George Arakelian Farms, Inc.*, 536 F.2d 856, 860 (9th Cir. 1976) (finding a law irrational where it was "grossly excessive" in relation to government interest).

Finally, although Intervenor-Defendants do not offer any other interest to support the Hospitalization Requirement, they attempt to rely on *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (4th Cir. 2000). In that case, the Fourth Circuit held that it is rational to "distinguish[] between abortion services and other medical services when regulating physicians or women's healthcare." *Id.* at 173. But the *Greenville* court relied on "the State's interest in protecting prenatal life" for its holding, *id.*, and Intervenor-Defendants do not argue that the Hospitalization Requirement promotes this interest. Nor could they, since the General Assembly has already determined that abortions after the twelfth week of pregnancy in cases of rape or incest or upon diagnosis of a life-limiting anomaly are

permissible. *See* N.C. Gen. Stat. §§ 90-21.81B(3)–(4). The Hospitalization Requirement merely governs the clinical setting for legal abortions.

Although “[a]bortion may well be a special case” in some regards, “it cannot be so special a case that all other professional rights and medical norms go out the window.” *Stuart v. Camnitz*, 774 F.3d 238, 255–56 (4th Cir. 2014). *Greenville* does not abrogate the requirement that an abortion regulation must be rationally related to a legitimate governmental interest to pass constitutional muster. The Hospitalization Requirement should be preliminarily enjoined because it fails this test.

## **B. The IUP Documentation Requirement**

### *i. Vagueness*

Plaintiffs argue that the Act is unconstitutionally vague because it fails to provide notice as to when medication abortion is lawful for pregnancies of unknown location. “To survive a vagueness challenge, a statute must give a person of ordinary intelligence adequate notice of what conduct is prohibited and must include sufficient standards to prevent arbitrary and discriminatory enforcement.” *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 272 (4th Cir. 2019) (en banc). For statutes that, like the IUP Documentation Requirement, may carry the threat of criminal penalties, a stricter standard applies. *See id.* (“Less clarity is required in purely civil statutes . . .”).<sup>6</sup> And even if

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<sup>6</sup> Intervenor-Defendants’ argument that the scienter requirements of the criminal prohibitions ameliorate the vagueness concerns is not persuasive. They fail to explain how the scienter requirements for the fetal homicide and unlawful abortion statutes resolves the conflict in the IUP Documentation Requirement. *See* Pl. Reply, DE 69 at 8.

criminal penalties do not apply, failing to comply with the intrauterine documentation requirement subjects the physician to professional discipline, thus warranting, at a minimum, a relatively strict standard. *Id.* at 273 (noting a “relatively strict test” applies to quasi-criminal laws that have stigmatizing effects).

As interpreted by Intervenor-Defendants, the Act is self-contradictory. On one hand, it provides that medication abortion is lawful up to twelve weeks of pregnancy. On the other, it requires physicians to “[d]ocument in the woman’s medical chart the . . . existence of an intrauterine pregnancy,” N.C. Gen. Stat. § 90-21.83B(a)(7). Intervenor-Defendants take the position that visual confirmation by ultrasound is required to comply with this requirement, DE 65 at 20, but the evidence in this case supports the conclusion that intrauterine pregnancy cannot be visually confirmed in the early weeks of pregnancy, when an intrauterine embryo cannot always be detected by ultrasound. *See* First Farris Decl., DE 49-1 ¶ 49; First Boraas Decl., DE 49-2 ¶ 41; Bane Dep. 108:14–15. Intervenor-Defendants’ interpretation would therefore mean that medication abortion is banned in the earliest weeks of pregnancy, despite the Act’s clear intent that abortion remain lawful in North Carolina until after the twelfth week of pregnancy.

On its face, the Act fails to give Plaintiffs notice as to whether they can provide medication abortion before an intrauterine pregnancy can be seen on an ultrasound. Thus, it “fails to provide any standard of conduct by which persons can determine whether they are violating the statute” and “invite[s] arbitrary enforcement.” *Manning*, 930 F.3d at 274, 276. It is, therefore, impermissibly vague. However, to avoid this constitutional infirmity

and internal contradiction within the Act itself, this Court will construe the IUP Documentation Requirement to require that a physician document *whether* an intrauterine pregnancy is visible by ultrasound—but even if an intrauterine pregnancy is not yet visible, they may still perform a medication abortion through twelve weeks of pregnancy. So construed, the IUP Documentation Requirement does not contradict the provision of the Act that permits medication abortion through the twelfth week of pregnancy.

*ii. Substantive Due Process*

To the extent that the IUP Documentation Requirement prohibits providing medication abortion to patients with pregnancies of unknown location, Plaintiffs also argue that it violates substantive due process because it does not satisfy the rational basis standard. Intervenor-Defendants argue that the IUP Documentation Requirement is rationally related to the State’s interest in the protection of maternal health by “ensuring that physicians do not prescribe chemical abortion drugs to a woman suffering from an ectopic pregnancy.” DE 65 at 21. The Court agrees that this is a legitimate governmental interest and turns to the question of whether the IUP Documentation Requirement is rationally related to that interest.

Plaintiffs have presented evidence that for patients with pregnancies of unknown location who are deemed to be at low risk of ectopic pregnancy, providing medication abortion while *simultaneously* using additional testing to rule out ectopic pregnancy is safe, based both on published research and PPSAT’s experience. *See supra* Background, Part II. Drs. Bane and Wubbenhorst conceded that ectopic screening protocols that use

ultrasounds, medical histories, and serial hCG testing are appropriate. Bane Dep. 117:22–118:25, 143:4–11; Wubbenhorst Dep. 143:22–25. Dr. Bane agreed that patients with pregnancies of unknown location in stable condition do not immediately need to be referred to the emergency room, even those with minor complaints such as “abdominal pain or some bleeding,” Bane Dep. 117:22–118:25—and of course, the IUP Documentation Requirement itself does not require such referral. Further, both Drs. Wubbenhorst and Bane testified that they believed that PPSAT does not require an ultrasound in every case, demonstrating a lack of understanding of both North Carolina law and PPSAT’s protocols. *Id.* at 112:5–8; Wubbenhorst Dep. at 145:2–7. The Court therefore credits Plaintiffs’ experts’ testimony that PPSAT’s protocols are safe and evidence-based.

Plaintiffs have introduced evidence that waiting to provide medication abortion until an intrauterine pregnancy is visible by ultrasound does not lead to earlier or more accurate diagnosis of ectopic pregnancy than providing a medication abortion and concurrently testing for ectopic pregnancy, but rather leads only to delay. First Farris Decl., DE 49-1 ¶ 59; First Boraas Decl., DE 49-2 ¶ 50. One study relied on by Plaintiffs’ experts found that providing a medication abortion simultaneously with screening for an ectopic pregnancy led to *faster* detection of ectopic pregnancies than waiting until an intrauterine pregnancy is visible. First Boraas Decl., DE 49-2 ¶ 46; Boraas Rebuttal Decl., DE 69-1 ¶ 49. Plaintiffs have also introduced evidence that many patients prefer medication abortion to procedural abortion for a variety of reasons, and PPSAT’s protocol allows them to receive their desired method of care in a timely manner—which patients are generally anxious to do, particularly

when state law will prevent them from obtaining an abortion after the twelfth week of pregnancy. First Farris Decl., DE 49-1 ¶ 19; First Boraas Decl., DE 49-2 ¶ 43; Boraas Dep. 167:19–168:3; Farris Dep. 148:14–149:11, 152:24–153:11. Additionally, denying Plaintiffs the ability to provide medication abortion to patients with pregnancies of unknown location would not necessarily lead to any patient seeking screening for a potential ectopic pregnancy, at PPSAT or elsewhere.

Intervenor-Defendants argue that Plaintiffs’ protocols are unsafe because mifepristone is contraindicated for ectopic pregnancy. DE 65 at 21–22. But the FDA label cited by Intervenor-Defendants actually states that mifepristone is contraindicated for patients with “*confirmed/suspected* ectopic pregnancy,” FDA Mifeprex Label, DE 65-2 at 1 (emphasis added), not for patients who have been clinically deemed low-risk for ectopic pregnancy—and low-ectopic-risk patients are the ones Plaintiffs would treat but for the IUP Documentation Requirement. *See* Farris Dep. 107:3–8, 109:14–21, 110:5–9, 163:8–17. And Dr. Wubbenhorst conceded that mifepristone is contraindicated for patients with ectopic pregnancy not because it harms them (it does not), but rather because it does not *treat* ectopic pregnancy. Wubbenhorst Dep. 143:19–21; *see also* Farris Dep. 155:11–14; Boraas Rebuttal Decl., DE 69-1 ¶ 50. Thus, merely preventing a patient with a pregnancy of unknown location from taking mifepristone is not, by itself, rationally related to advancing the safety of patients with ectopic pregnancies.<sup>7</sup>

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<sup>7</sup> Intervenor-Defendants also argue that medication abortion is generally unsafe as compared to procedural abortion and insinuate that PPSAT’s provision of medication abortion through eleven weeks’ gestation is unsafe. DE 65 at 3; Bane Decl., DE 65-3 ¶ 35;

Intervenor-Defendants also argue that a patient may mistake ectopic rupture for the bleeding and cramping associated with a medication abortion. But both sides' experts agree that the symptoms of ectopic rupture and those associated with medication abortion are typically distinguishable. Wubbenhorst Dep. 182:16–20; Bane Dep. 120:3–5, 120:17; Boraas Rebuttal Decl., DE 69-1 ¶ 53. And Plaintiffs introduced testimony and documentary evidence that PPSAT educates patients about these symptoms and encourages them to contact PPSAT immediately if they experience any. Farris Rebuttal Decl., DE 69-2 ¶ 12; Farris Dep. 125:2–9, 164:9–24; *see* Bates 0119–0120 (PPSAT patient education materials regarding pregnancy of unknown location and ectopic pregnancy).

The Court credits the testimony of Dr. Farris, who has experience providing abortions to patients with pregnancies of unknown location in North Carolina, and of Dr. Boraas, who has this experience outside of North Carolina and has also specifically researched the safety of medication abortion for patients with pregnancies of unknown location. The evidence offered in this case establishes that providing medication abortion to patients with a pregnancy of unknown location is safe, evidence-based, and may actually

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Wubbenhorst Decl., DE 65-1 ¶¶ 33–34. However, Plaintiffs persuasively refute the study that Intervenor-Defendants' experts cite concerning the relative safety of medication abortion. Boraas Rebuttal Decl., DE 69-1 ¶ 14. Nor is there any issue with Plaintiffs' provision of medication abortion through eleven weeks. The off-label usage of mifepristone has been shown to be safe at more advanced gestations than what appears on the FDA-approved label, and off-label drug prescription is common in the medical field and practiced by many physicians including Drs. Bane and Wubbenhorst. *Id.* ¶ 52; Bane Dep. 31:25–32:15; Wubbenhorst Dep. 174:15–18. Indeed, the General Assembly explicitly amended the Act to permit medication abortions at later gestational ages than what is indicated on the FDA label.

lead to earlier detection of ectopic pregnancies. Based on the evidence presented, the Court concludes that the IUP Documentation Requirement is not rationally related to the State's interest in patient health and safety, and Plaintiffs are therefore likely to succeed on their challenge to the IUP Documentation Requirement.

## **II. Irreparable Harm**

If the Hospitalization and IUP Documentation Requirements take effect, Plaintiffs and their patients will suffer irreparable harm. Plaintiffs and their patients would be denied their constitutional rights to due process and equal protection, Verified First Am. Compl. for Declaratory & Inj. Relief ("First Am. Compl.") DE 42 ¶¶ 82–86, which alone is sufficient to establish irreparable harm. *See Leaders of a Beautiful Struggle v. Balt. Police Dep't*, 2 F.4th 330, 346 (4th Cir. 2021) (en banc). The provisions would also delay or prevent patients' access to abortion, forcing some to remain pregnant against their will and to give birth without adequate prenatal, obstetric, or postpartum medical support, and interfere with Plaintiffs' ability to practice evidence-based, patient-centered medicine. *See* First Farris Decl., DE 49-1 ¶ 81; First Am. Compl., DE 42 ¶¶ 15–16. Delaying access to care could cause additional harm to patients because the risks associated with abortion, although small, increase with gestational age. Boraas Rebuttal Decl., DE 69-1 ¶ 19; Wubbenhorst Decl., DE 65-1 ¶ 38; Bane Decl., DE 65-3 ¶ 35. The harms created by the challenged provisions would be borne especially by families with low incomes, North Carolinians of color, and rural North Carolinians, who already face inequities in access to health care. First Farris Decl., DE 49-1 ¶ 10. These are harms "that cannot be compensated

by money damages at a later trial.” *Int’l Refugee Assistance Project v. Trump*, 265 F. Supp. 3d 570, 629 (D. Md. 2017), *vacated sub nom. Trump v. Int’l Refugee Assistance Project*, 138 S. Ct 2710 (2018).

In particular, the Hospitalization Requirement would delay and deny access to urgently needed health care for some of the most vulnerable populations—survivors of sexual violence and patients with life-limiting fetal diagnoses. By preventing patients from seeking abortions in outpatient settings after the twelfth week, the Hospitalization Requirement would increase the cost of abortions, limit the number of available providers, and delay access to care. First Farris Decl., DE 49-1 ¶¶ 67, 69–71. Those harms and attendant suffering would fall particularly acutely on those who have survived sexual violence or are in abusive relationships, who may find it difficult or even impossible to escape their abuser’s control long enough to access an abortion. *Id.* ¶ 66. Moreover, physicians who primarily practice in hospital settings may be less experienced in procedural abortions, forcing patients who have abortions at hospitals to undergo induction abortions—which can be far more expensive, time-consuming, and physically arduous than the D&Es routinely provided in outpatient settings, *id.* ¶ 74—or to undergo a deeper level of sedation, even if they would have preferred to have more minimal sedation that could have been safely provided in an outpatient setting. *See id.* ¶¶ 35–36.

The IUP Documentation Requirement will also harm patients by delaying their access to abortions, unnecessarily exposing them to increased medical risk, and compelling them to consider a procedural abortion even if medication abortion may offer important

advantages over procedural abortion for them. *Id.* ¶ 19; First Am. Compl., DE 42 ¶¶ 50–52. For example, survivors of rape or other sexual abuse may choose medication abortion to feel more in control and to avoid further trauma from having instruments placed in their vaginas. First Farris Decl., DE 49-1 ¶ 19; First Am. Compl., DE 42 ¶ 50.

### **III. The Balance of the Equities and the Public Interest**

Finally, the balance of equities and public interest weigh heavily in favor of injunctive relief. Defendants are “in no way harmed by issuance of a preliminary injunction which prevents [them] from enforcing” the provisions of the Act that are “likely to be found unconstitutional.” *Newsom ex rel. Newsom v. Albemarle Cnty. Sch. Bd.*, 354 F.3d 249, 261 (4th Cir. 2003); *see also Legend Night Club v. Miller*, 637 F.3d 291, 303 (4th Cir. 2011) (recognizing that “upholding constitutional rights is in the public interest”). Nor have Intervenor-Defendants provided any evidence that any patient in North Carolina—or anywhere—with a pregnancy of unknown location has been harmed by the performance of a medication abortion. Their expert Dr. Wubbenhorst admitted that she is unaware of any early medication abortion patients who have experienced negative outcomes from an ectopic pregnancy as a result of PPSAT’s protocol. Wubbenhorst Dep. 153:18–22. Plaintiffs safely provided abortions after the twelfth week of pregnancy and to patients with pregnancies of unknown location prior to the passage of the Act. First Farris Decl., DE 49-1 ¶ 12; Farris Dep. 75:4–6.

In contrast, Plaintiffs and their patients would suffer grave harm in the absence of an injunction. *See supra* Analysis, Part II. In addition to preserving constitutional rights,

an injunction would advance North Carolinians’ health and safety by allowing abortion access without the challenged restrictions impeding Plaintiffs’ ability to continue to provide evidence-based, patient-centered care. *See Fruth, Inc. v. Pullin*, No. 3:15-16266, 2015 WL 9451066, at \*8 (S.D. W. Va. Dec. 23, 2015) (observing that “an injunction here will safeguard the public health and thereby serve the public interest”).

### CONCLUSION

For the foregoing reasons, Plaintiffs’ Amended Motion for Preliminary Injunction is hereby **GRANTED**. In the Court’s discretion, the bond requirement under Rule 65(c) is waived.

This the \_\_\_\_ day of \_\_\_\_\_, 2023.

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United States District Judge

Dated: September 12, 2023

Respectfully submitted,

*/s/ Kristi Graunke*

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### **CERTIFICATE OF SERVICE**

I hereby certify that, on September 12, 2023, I electronically filed the foregoing with the clerk of the court by using the CM/ECF system, which served notice of this electronic filing to all counsel of record.

/s/ Hannah Swanson

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